CLAIMS

What is claimed is:

1. A composite comprising:
   a) amniotic membrane; and
   b) a plurality of retinal pigment epithelial cells or retinal pigment epithelial equivalent cells present at the amniotic membrane.

2. The composite of Claim 1, wherein the amniotic membrane is epithelially denuded.

3. The composite of Claim 1, wherein the amniotic membrane is intact amniotic membrane comprising a basement membrane and a stroma.

4. The composite of Claim 3, wherein the amniotic membrane is present as a membrane treated on at least one side.

5. The composite of Claim 4, wherein the treatment is excimer laser ablation to thin the stromal side or excimer laser ablation to thin the basement membrane side.

6. The composite of Claim 4, wherein the treatment is laser treatment to alter the thickness of the stromal side.

7. The composite of Claim 4, wherein the treatment is addition of mesenchymal cells to the stromal side.

8. The composite of Claim 7, wherein the cells are fibroblasts.

9. The composite of Claim 1, wherein the amniotic membrane is human amniotic membrane.

10. The composite of Claim 1, wherein the number of retinal pigment epithelial equivalent cells at the amniotic membrane is from about 16,000 to about 20,000 per 4 mm^2.

11. The composite of Claim 1, wherein the number of retinal pigment epithelial equivalent cells at the amniotic membrane is about 4,000 per 4 mm^2.

12. The composite of Claim 1, wherein the retinal pigment epithelial equivalent cells comprise iris pigment epithelial cells.

13. The composite of Claim 1, wherein a source of the retinal pigment epithelial equivalent cells comprises cells that have been immortalized by viral agents or non-viral agents.

14. The composite of Claim 1, wherein a source of the retinal pigment epithelial equivalent cells comprises at least one stem cell induced *in vitro* to differentiate into a retinal pigment epithelial cell.

15. The composite of Claim 14, wherein the stem cells comprise adult stem cells.

16. The composite of Claim 14, wherein the stem cells comprise embryonal stem cells.

17. The composite of Claim 15, wherein the adult stem cells comprise peripheral blood cells or bone marrow cells.

18. The composite of Claim 1, wherein a source of the retinal pigment epithelial equivalent cells comprises at least one bioengineered cell induced *in vitro* to differentiate into a retinal pigment epithelial cell.

19. The composite of Claim 1, wherein the retinal pigment epithelial equivalent cells retain the retinal pigment epithelial phenotype.

20. The composite of Claim 1, wherein the retinal pigment epithelial equivalent cells present at the amniotic membrane comprise cultured cells.

21. The composite of Claim 1, wherein the retinal pigment epithelial equivalent cells comprise cells derived from neural retinal cells or from ciliary body.

22. The composite of Claim 21, wherein the neural retinal cells comprise rod cells or cone cells.

23. The composite of Claim 1, further including a pharmaceutically active molecule.

24. The composite of Claim 23, wherein the pharmaceutically active molecule comprises at least one substance independently selected from the group consisting of growth factors, enzymes, and therapeutic drugs.

25. The composite of Claim 24, wherein the growth factor is selected from the group consisting of retinal pigment epithelium-derived growth factor and transforming growth factor-beta.

26. The composite of Claim 23, wherein the pharmaceutically active molecule is interleukin-10.

27. A kit comprising:

a) amniotic membrane;

b) a plurality of retinal pigment epithelial cells or retinal pigment epithelial equivalent cells present at the amniotic membrane;

c) a buffer medium or a culture medium; and

d) optionally, instructions for simultaneous, separate, or sequential use of at least one component of the kit for treating a retinal disease.

28. The kit according to Claim 27, further comprising at least one pharmaceutically active agent.

29. The kit according to Claim 28, wherein the pharmaceutically active agent comprises at least one substance independently selected from the group consisting of growth factors, enzymes, and therapeutic drugs.

30. The kit of Claim 29, wherein the growth factor is selected from the group consisting of retinal pigment epithelium-derived growth factor and transforming growth factor-beta.

31. The kit of Claim 28, wherein the pharmaceutically active agent is interleukin-10.

32. The kit according to Claim 27, wherein the retinal pigment epithelial equivalent cells comprise bioengineered cells.

33. A method of forming a composite comprising the steps of:

a) applying at least one retinal pigment epithelial cell or retinal pigment epithelial equivalent cell to an amniotic membrane; and

b) culturing the retinal pigment epithelial cell or retinal pigment epithelial equivalent cell on the membrane under conditions suitable for growth for a period of time sufficient to produce a plurality of cultured cells.

34. The method of Claim 33, wherein the number of cultured cells on the membrane is from about 16,000 to about 20,000 per 4 mm^2.

35. A method of inducing an excised or cultured retinal pigment epithelial cell or retinal pigment epithelial equivalent cell to express or to maintain the phenotype of retinal pigment epithelial cells, the method comprising the steps of:

a) contacting amniotic membrane with the retinal pigment epithelial cell or retinal pigment epithelial equivalent cell;

b) culturing the retinal pigment epithelial cell or retinal pigment epithelial equivalent cell on the membrane under conditions suitable for growth for a period of time sufficient to produce a plurality of cultured cells; and either

c) contacting the cultured cells with an effective amount of an agent that raises the intracellular calcium ion concentration to a level sufficient to induce or maintain the phenotype of retinal pigment epithelial cells; or

d) exposing the membrane comprising cultured cells to an air-fluid interface for a period of time sufficient to induce or maintain the phenotype of retinal pigment epithelial cells.

36. The method of Claim 35, wherein both steps c and d are performed.

37. The method of Claim 35, wherein in step c, the intracellular calcium ion concentration is elevated to a concentration of from about 0.5 mM to about 2.0 mM.

38. The method of Claim 35, wherein in step c, the intracellular calcium ion concentration is elevated to about 1.8 mM.

39. The method of Claim 35, wherein the step of culturing the retinal pigment epithelial cell or retinal pigment epithelial equivalent cell on the membrane is continued until the cells reach confluence.

40. The use of human amniotic membrane to promote growth and differentiation of at least one retinal pigment epithelial equivalent cell to a plurality of cells that express the phenotype of retinal pigment epithelial cells.

41. A method of delivering a plurality of retinal pigment epithelial cells to a target site in a subretinal space in an individual in need thereof, comprising:

a) forming at least one hole in a retina of the individual, or at least partially detaching the retina to access the subretinal space;

b) inserting through the hole a composite comprising amniotic membrane and the retinal pigment epithelial cells present at the membrane; and

c) positioning the composite at the target site.

42. A method for treating a retinal disease, comprising inserting in a subretinal space of a patient in need thereof a composite comprising amniotic membrane and a plurality of retinal pigment epithelial cells present at the membrane.

43. The method of Claim 42, wherein the number of retinal pigment epithelial cells present at the membrane is from about 16,000 to about 20,000 per 4 mm^2.

44. The method of Claim 42, wherein the retinal disease that is treated is age-related macular degeneration.

45. The method of Claim 42, wherein the retinal disease that is treated is selected from the group consisting of retinal detachment, gyrate atrophy, and choroideremia.

46. The method of Claim 42, wherein the amniotic membrane is human amniotic membrane.

47. The method of Claim 42, wherein the retinal pigment epithelial cells comprise cells cultured on the amniotic membrane.

48. The method of Claim 42, wherein the composite further comprises a pharmaceutically active molecule.

49. The method of Claim 48, wherein the pharmaceutically active molecule is selected from the group consisting of growth factors, enzymes, and therapeutic drugs.

50. The use of human amniotic membrane for transplanting retinal pigment epithelial cells or iris pigment epithelial cells to a subretinal space, to prevent or decrease a sensitizing of a recipient to alloantigens and to retinal pigment epithelial-specific autoantigens.

51. The use of human amniotic membrane to inhibit fibrosis following transplantation of retinal pigment epithelial cells or iris pigment epithelial cells to the subretinal space.

52. The use of human amniotic membrane and at least one retinal pigment epithelial cell for the manufacture of a composition for treatment of a retinal disease in a patient suffering from, or at risk of developing the disease.